

Message Text

UNCLASSIFIED

PAGE 01 STATE 094431

62

ORIGIN HEW-06

INFO OCT-01 EA-10 ISO-00 OES-05 EB-07 COME-00 /029 R

09

DRAFTED BY:DHEW/FDA/JRWEINROTH M.D.

APPROVED BY:OES/SCI/BMP:MBEAUBIEN

DHEW/OIH/MACODDING

EA/J:CDUNKERLEY(INFO)

----- 029832

R 241526Z APR 75

FM SECSTATE WASHDC

TO AMEMBASSY TOKYO

UNCLAS STATE 094431

E.O. 11652: N/A

TAGS: OGEN, ETRD, TBIO, JA

SUBJECT: GDA ADVISORY-DEFECTIVE DIAGNOSTIC PRODUCT-SUSPECT CULTURE
MEDIA

FDA ADVISES THAT THE PRODUCT SORANASE, MANUFACTURED BY
DIAGNOSTIC RESEARCH, INC. (DIVISION OF CORNING GLASS WORKS)
25 LUMBER ROAD, ROSLYN, N.Y. 11576; LOT NOS.: 740506,
740524, 740625, 740715, 740723, 740805, 740806, 740830,
740913, 741015, 741108, 741211, 741212, 750102, 750203,
ARE BEING RECALLED TO THE CONSIGNEE (USER) LEVEL.

SORANASE CONSISTS OF A 9ML. GLASS, CONSTRICTED, SCREW-
CAPPED TUBE CONTAINING 4 MEDIA IN ONE TUBE FOR DIFFERENTI-
ACTION OF ENTEROBACTER AEROGENES, ENTEROBACTER HAFNIA,
SERRATIA MARCESCENS, SERRATIA LIQUEFACIENS, AND NON-H2S
SALMONELLA. THE TUBES BEAR THE PRODUCT NAME, LIST OF
REACTIVE INGREDIENTS, USES, LOT NUMBER, AND EXPIRATION
DATE. THE TUBES ARE PACKED 40 PER CARTON AND A BOOKLET
OF INSTRUCTIONS IS INCLUDED IN THE BOX. THE PRODUCT
BEING RECALLED WAS MANUFACTURED AND DISTRIBUTED BETWEEN
MAY 1974 AND MARCH 1975.

THE REASON FOR THE RECALL IS THAT A QUESTIONABLE REACTION
UNCLASSIFIED

UNCLASSIFIED

PAGE 02 STATE 094431

OCCURS IN THE L-ARABINOSE PORTION OF THE MEDIA USED IN

DIFFERENTIATING BETWEEN SERRATIA MARCESCENS, AND SERRATIA
LIQUEFACIENS.

POST IS REQUESTED TO DETERMINE IF CONSIGNEE HAS BEEN
NOTIFIED OF RECALL BY MANUFACTURER AND IS FAMILIAR WITH
DETAILS THEREOF.

FOREIGN CONSIGNEE AS FOLLOWS:

IWAKI & CO., LTD., 1-NIHOMBASHI HONCHO, 4-CHOME,
CHUO-KU, TOKYO, JAPAN. END
KISSINGER

UNCLASSIFIED

NNN

Message Attributes

Automatic Decaptioning: X
Capture Date: 01 JAN 1994
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: RECALL, ELECTRONIC EQUIPMENT, FOOD & DRUG REGULATIONS
Control Number: n/a
Copy: SINGLE
Draft Date: 24 APR 1975
Decaption Date: 01 JAN 1960
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Authority: n/a
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01 JAN 1960
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1975STATE094431
Document Source: CORE
Document Unique ID: 00
Drafter: DHEW/FDA/JRWEINROTH M.D.
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Film Number: D750145-0156
From: STATE
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1975/newtext/t19750420/aaaaasis.tel
Line Count: 72
Locator: TEXT ON-LINE, ON MICROFILM
Office: ORIGIN HEW
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
Page Count: 2
Previous Channel Indicators: n/a
Previous Classification: n/a
Previous Handling Restrictions: n/a
Reference: n/a
Review Action: RELEASED, APPROVED
Review Authority: ShawDG
Review Comment: n/a
Review Content Flags:
Review Date: 08 JUL 2003
Review Event:
Review Exemptions: n/a
Review History: RELEASED <08 JUL 2003 by SilvaL0>; APPROVED <03 FEB 2004 by ShawDG>
Review Markings:

Margaret P. Grafeld
Declassified/Released
US Department of State
EO Systematic Review
05 JUL 2006

Review Media Identifier:
Review Referrals: n/a
Review Release Date: n/a
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
Secure: OPEN
Status: NATIVE
Subject: GDA ADVISORY-DEFECTIVE DIAGNOSTIC PRODUCT-SUSPECT CULTURE MEDIA
TAGS: OGEN, ETRD, TBIO, JA, FDA
To: TOKYO
Type: TE
Markings: Margaret P. Grafeld Declassified/Released US Department of State EO Systematic Review 05 JUL 2006